ONE HUNDRED FIFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT
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May 19, 1998

VIA FACSIMILE 301-443-2567

Michael A. Friedman, Acting Commissioner
U.S. Department of Health and Human Services
Food and Drug Administration
Parklawn Building - 5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Friedman:

During the Government Reform and Oversight hearing held on April 22, 1998, questions were directed to you pursuant to media reports that fenfluramine was being used in non-therapeutic scientific research on economically disadvantaged children. At the time of the hearing you stated that it would be necessary to conduct a deeper inquiry into the matter before you could adequately respond to the issues raised. Presumably, you have had an opportunity to gather further information, and in light of the unanswered questions, I would appreciate your prompt response to this request for information and documents.

Please provide the following documents relevant to fenfluramine use in children and adults:

1. Summary of all New Drug Applications (NDA) for fenfluramine
2. All FDA memoranda and reports concerning cardiotoxicity of fenfluramine
3. All FDA memoranda and reports concerning neurotoxicity of fenfluramine
4. All FDA memoranda and reports concerning fenfluramine and children
5. All FDA memoranda and reports concerning the withdrawal of fenfluramine from the market
6. Complete up-to-date Spontaneous Reporting System summary for fenfluramine adverse drug event reports to the FDA on computer disk
7. FDA regulations, and policies on permitting the off-label use of drugs in experiments on children

8. All FDA communications to researchers, research institutes, universities or other research bodies concerning the use of fenfluramine for research purposes following its withdrawal from the market.

Please provide written answers to the following:

1. What responsibility does the FDA have with regard to monitoring the experimental use of drugs on children?

2. What responsibility does the FDA have for setting standards and monitoring off-label use of drugs for experimental (nontherapeutic) purposes in children?

3. What are the implications and dangers of off-label use of potentially dangerous drugs for experimental purposes on children?

4. What are the implications and dangers of giving children drugs for experimental purposes that have not been approved for use in children?

5. How can there be any certainty that the drugs will not prove especially harmful to children when they have not been tested and FDA-approved for children?

6. Why did the FDA allow the use of fenfluramine for experimental purposes in healthy children when it is known to be neurotoxic and cardiotoxic?

7. Why didn't the FDA require a new round of IRB review for the use of fenfluramine in experimental research in children when the drug was withdrawn from the market?

The requested information should be provided no later than the close of business, June 4, 1998. If you have any questions regarding this request, please contact Committee Counsel Laurie S. Taylor at (202) 225-5074.

Sincerely,

Dan Burton
Chairman

cc: The Honorable Chris Shays